

EX A

**FOIA CONFIDENTIAL TREATMENT REQUEST BY  
BIODELIVERY SCIENCES INTERNATIONAL, INC.  
IRS EMPLOYER IDENTIFICATION NUMBER 35-2089858  
CONFIDENTIAL TREATMENT REQUESTED WITH RESPECT TO CERTAIN PORTIONS HEREOF  
DENOTED WITH “\*\*\*”**

**MASTER SERVICES AGREEMENT**

This Master Services Agreement (this “Agreement”), with an Effective Date of September 30, 2013, will set forth the terms and conditions between BioDelivery Sciences International, Inc., 801 Corporate Center Drive, Raleigh, NC 27607 (hereinafter “BDSI”), and Quintiles Commercial US, Inc., 10 Waterview Boulevard, Parsippany, NJ 07054 (hereinafter “Quintiles”).

**Background:**

A. BDSI is in the business of developing, manufacturing and/or distributing pharmaceutical and/or biotechnology products (“BDSI Product(s)”). Quintiles is in the business of providing sales, marketing, consulting, strategic advisory, outsourcing implementation, educational and alternative commercialization services for the pharmaceutical, healthcare and biotechnology industries.

B. BDSI and Quintiles desire to enter into this Agreement to provide the terms and conditions upon which BDSI may engage Quintiles and its corporate Affiliates from time-to-time to provide contract sales, marketing, consulting, strategic advisory, outsourcing implementation, educational and alternative commercialization services for individual projects by executing individual Work Orders (as defined below) specifying the details of the services and the related terms and conditions.

**Agreement:**

**1. Definitions**

- 1.1 “Affiliate” shall mean any corporation or business entity controlled by, controlling, or under common control with a party to this Agreement as of the Effective Date. For this purpose, “control” shall mean direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or income interest in such corporation or other business entity, or such other relationship as, in fact, constitutes actual control.
- 1.2 “FDA” shall mean the US Food and Drug Administration.
- 1.3 “Fees” shall mean \*\*\* agreed to by the parties pursuant to applicable executed Work Orders that is payable to Quintiles in return for Services performed pursuant to such Work Order. Fees shall \*\*\*.
- 1.4 “Pass-Through Expenses” shall mean the \*\*\* incurred by Quintiles or Quintiles personnel in the course of providing Services and evidenced \*\*\*, in accordance with \*\*\* or the \*\*\*.
- 1.5 “Project” shall mean the complete task or set of tasks described in a specific Work Order.

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- 1.6 “Services” shall mean the responsibilities, obligations and activities which are to be performed by Quintiles, as they are described in this Agreement and in specific Work Orders.
- 1.7 “Term” and “Project Term” shall have the meanings described in Section 10.1.
- 1.8 “Work Order” shall have the meaning described in Section 2.2.

**2. Scope of Agreement; Services to be Provided; Work Orders; Project Teams.**

- 2.1 Scope of Agreement. This Agreement allows the parties to contract for multiple Projects through the issuance of multiple Work Orders. This Agreement covers the provision of strategic advisory, consulting, and commercialization services by Quintiles and Quintiles’ corporate Affiliates (see Section 10) when requested by BDSI and agreed to by Quintiles as set forth in the relevant Work Order. BDSI shall, in its sole discretion, determine when and whether to offer projects to Quintiles and its corporate Affiliates, including the decision whether or not to enter into a specific Work Order.
- 2.2 Work Orders. The specific details and tasks of each Project shall be separately negotiated and specified in writing on terms and in a form acceptable to the parties (each such writing, a “Work Order”). The first Work Order is of even date hereof and subsequently issued Work Orders may follow the same basic template. Each Work Order will include, as appropriate, \*\*\*. Each Work Order shall be subject to all of the terms and conditions of this Agreement, in addition to the specific details set forth in the Work Order. To the extent any terms or provisions of a Work Order conflict with, expand or contract the terms and provisions of this Agreement, the terms and provisions of this Agreement shall control, unless the Work Order expressly and specifically states an intent to supersede the Agreement on a specific matter (but then only with respect to the particular Work Order and with respect only to the matter so specified). A change in a Work Order shall be evidenced by an amendment to the relevant Work Order duly executed by BDSI and Quintiles in form acceptable to both parties. Quintiles will manage and administer each Project in accordance with the specifications and timelines contained in each Work Order.

**3. Payment of Fees and Pass-Through Expenses.**

- 3.1 BDSI shall pay Quintiles the Fees and Pass-Through Expenses expressly described in each Work Order. Unless otherwise agreed in a particular Work Order, Quintiles will invoice BDSI \*\*\* for the Fees and Pass-Through Expenses relating to the Project. Each invoice shall be supported by a detailed expense report, and supporting documentation will be made available to BDSI upon request. Depending on the \*\*\* of the \*\*\* and based upon \*\*\* to between the parties, \*\*\* agrees that a \*\*\* for Quintiles to \*\*\*. Any such prepayment shall be specified in the applicable Work Order.

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- 3.2 BDSI shall make payment for all undisputed amounts of invoiced Fees within \*\*\* after the receipt of \*\*\* invoice (“Due Date”). All invoices shall be deemed received \*\*\* after the date postmarked if sent by mail, on the date sent if they are sent electronically or by facsimile, and \*\*\* after the date they are sent if delivered by a reputable overnight delivery service. Quintiles reserves the right to impose, and BDSI agrees to pay if imposed by Quintiles, \*\*\* (or if less, the maximum amount permitted by law) of all undisputed amounts owing hereunder, which are outstanding \*\*\* from the Due Date of the invoice.
- 3.3 If any portion of an invoice is disputed, BDSI shall pay the undisputed amounts by the Due Date, and the parties shall use good faith efforts to reconcile the disputed amount for payment as soon as practicable.
- 3.4 If the period of non-payment of an undisputed amount exceeds \*\*\* past the Due Date, Quintiles may, at its sole discretion and without prejudice to any other rights or remedies, exercise its right to give notice of a default in accordance with Section 10.3.
- 3.5 Payments shall be by wire-transfer or by check as follows:

**Postal Mail:**

Quintiles Commercial US, Inc.  
PO Box 601070  
Charlotte, NC 28260-1070

**Overnight Mail:**

Quintiles Commercial US, Inc.  
c/o Wells Fargo Bank  
\*\*\*

1525 West WT Harris Blvd - 2C2  
Charlotte, NC 28262

**Electronic Payment:**

\*\*\*

Quintiles Federal Employment ID Number is 22-3529314.

- 3.6 \*\*\* shall pay all applicable sales and use taxes solely pertaining to the Services, including all (and to the extent) applicable Goods and Services Tax (“GST”), Value Added Tax (“VAT”), local taxes, applicable duties, electronic delivery taxes, excise taxes, levies and import fees (collectively, “Taxes”) that are imposed by federal, state, or local law or legislation in connection with the provision of Services and that are not recoverable by \*\*\*. \*\*\* set forth in a Work Order are \*\*\*. Where Taxes are paid by \*\*\*, \*\*\* will provide an invoice showing the \*\*\*. Where any Taxes are paid directly to a tax authority or government by BDSI, BDSI shall not deduct this amount from any amount due to Quintiles. For the avoidance of doubt, the requirements of this provision \*\*\*.

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**4. Confidentiality and Ownership of Information.**

- 4.1 Each of the parties acknowledges that, in the course of performing its obligations hereunder, it may receive information from the other party which is proprietary to the disclosing party and which the disclosing party wishes to protect from public disclosure (“Confidential Information”). Quintiles and BDSI agree to retain in confidence, during the Term of this Agreement and any Work Order, and any subsequent renewals thereof, and thereafter for a period of \*\*\*, all Confidential Information disclosed to it by or on behalf of the other party, and that it will not, without the written consent of such other party, use Confidential Information for any purpose other than the purposes indicated herein. These restrictions shall not apply to Confidential Information that: (i) is or becomes public knowledge (through no fault of the receiving party); (ii) is made lawfully available to the receiving party by an independent third party, provided that such third party is not bound (to receiving party’s knowledge) by a confidentiality obligation with the disclosing party; (iii) is already in the receiving party’s possession at the time of receipt from the disclosing party (and such prior possession can be properly demonstrated by the receiving party), provided the source of such information was not bound (to the receiving party’s knowledge) by a confidentiality obligation with the disclosing party with respect to such information; (iv) is independently developed by the receiving party and/or Affiliates (and such independent development can be properly demonstrated by the receiving party); or (v) is required by law, regulation, rule, act or order of any governmental authority or agency or stock exchange on which the receiving party is traded to be disclosed by the receiving party, provided, however, if reasonably possible, such receiving party gives the disclosing party sufficient advance written notice to permit it to seek a protective order or other similar order with respect to such Confidential Information and, thereafter, the receiving party discloses only the minimum Confidential Information required to be disclosed in order to comply. In the event that the receiving party or its Representatives are requested or required (by oral questions, interrogatories, requests for information or documents in legal proceedings, subpoena, civil investigative demand or other similar legal process) to disclose any of the Confidential Information, the receiving party shall provide the disclosing party with prompt written notice of any such request or requirement so that the disclosing party may in its sole discretion seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement. If, in the absence of a protective order or other remedy or the receipt of a waiver by the disclosing party, the receiving party or its Representatives are nonetheless, in the opinion of competent, legal counsel, legally compelled to disclose Confidential Information to any tribunal, the receiving party or its Representatives may, without liability hereunder, disclose to such tribunal only that portion of the Confidential Information which such counsel reasonably advises is legally required to be disclosed, provided that the receiving party use its reasonable best efforts to preserve the confidentiality of the Confidential Information, including, without limitation, by cooperating with the disclosing party to obtain an appropriate protective order or other reliable assurance that confidential treatment will be accorded the Confidential Information by such tribunal; and provided further that the receiving party shall promptly notify the disclosing party of (i) the receiving party’s determination to make such disclosure and (ii) the nature, scope and contents of such disclosure.

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- 4.2 Quintiles and BDSI shall limit disclosure of the other party's Confidential Information to only those of their respective officers, representatives, agents, permitted subcontractors and employees (collectively "Representatives" and each a "Representative") who are directly concerned with the performance of this Agreement and have a legitimate need to know such Confidential Information ("Informed Persons"). The receiving party accepts responsibility for any breach of this Agreement by the receiving party or any of its Representatives and will undertake appropriate and reasonable precautions at its sole expense to ensure the protection, confidentiality and security of the Confidential Information, including assuring that all Informed Persons are aware of the confidential or proprietary nature of the Confidential Information and have themselves signed confidentiality agreements or otherwise legally bound by confidentiality. Upon receipt of notice of termination by BDSI, Quintiles shall return all BDSI Confidential Information to BDSI.
- 4.3 All BDSI patents, trade secrets, copyrights, trade names, trademarks, service marks, proprietary materials or intellectual property and all improvements to any of the foregoing (collectively "BDSI Property") used in connection with the Services provided pursuant to this Agreement or any Work Order shall remain the sole and exclusive property of BDSI, and Quintiles's rights to use such BDSI Property shall be limited to those permitted by this Agreement or any Work Order.
- 4.4 BDSI acknowledges that Quintiles and its Affiliates possess certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to analytical methods, procedures and techniques, computer technical expertise and software, and business practices, including, but not limited to the Quintiles Sales Force Automation System (SFA) or Quintiles' Customer Relationship Management System (CRM) as applicable, the Quintiles Pharmaceutical Selling System, and the Quintiles Sample Accountability System which have been independently developed by or for Quintiles and its Affiliates and which relates to the business or operations of Quintiles and its Affiliates (collectively "Quintiles Property"). BDSI and Quintiles agree that any Quintiles Property or improvements, modifications and enhancements thereto that are not specific to BDSI Confidential Information or BDSI Property, which are used, improved, modified or developed by Quintiles or its Affiliates under or during the term of this Agreement or any Work Order, are the sole and exclusive property of Quintiles.
- 4.5 The ownership of the disclosing party's Confidential Information shall at all times remain solely with the disclosing party (or the third party to whom the disclosing party owes a duty of confidentiality). Nothing herein shall be deemed to grant a license or other right, whether directly or by implication, estoppel or otherwise, to any Confidential Information disclosed pursuant to this Agreement except as herein expressly stated.

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- 4.6 The obligation of confidentiality shall survive for \*\*\* from expiration or earlier termination of this Agreement.
- 4.7 No party shall issue a press release or other public announcement relating to this Agreement or the activities contemplated herein without the prior written approval of the other party.
- 5. Independent Contractor Relationship.**
- 5.1 For the purposes of this Agreement and any Work Order, the parties hereto are independent contractors and nothing contained in this Agreement or any Work Order shall be construed to place them in the relationship of partners, principal and agent, employer and employee or joint venturers. Neither party shall have the power or right to bind or obligate the other party, nor shall either party hold itself out as having such authority.
- 5.2 No provision of this Agreement or any Work Order shall be deemed to create or imply any contract of employment between BDSI and any employee of Quintiles. All persons performing Services shall be employees of Quintiles, or permitted subcontractors engaged by Quintiles with prior consent of BDSI, and shall not be entitled to any benefits applicable to employees of BDSI.
- 5.3 Quintiles will be responsible for all financial, legal and compliance matters related to its employees, including, but notwithstanding, the obligation to: (i) maintain all necessary personnel and payroll records for Quintiles employees; (ii) compute wages and withhold applicable Federal, State and local taxes and Federal FICA payments for Quintiles employees; (iii) remit Quintiles employee withholdings to the proper governmental authorities and make employer contributions for Federal FICA and Federal and State unemployment insurance payments; (iv) pay net wages and fringe benefits, if any, directly to Quintiles employees; and (v) provide for appropriate employer's liability and Workers' Compensation insurance coverage in sufficient amounts to at a minimum cover its obligations hereunder and to comply with any applicable laws, regulations and ordinances.
- 5.4 Quintiles shall be responsible for management of all employer obligations in connection with Quintiles employees who perform the Services. Quintiles employees shall remain exclusively under the direct authority and control and responsibility of Quintiles. BDSI may be involved in providing training, direction or equipment to a Quintiles employee only in the manner and to the extent specifically described in a Work Order. The employer obligations of Quintiles shall include: (i) human resource issues, including establishment of employee policies, and administration of health and benefits plans, 401K plan, and other employee benefit plans; (ii) work performance and work behavior issues, including probationary period, periodic and annual appraisals, employee discipline and termination; (iii) administration of systems for time-keeping, payroll and employee expense reimbursement; (iv) day to day management of employment issues in connection with performance of the Services.

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**6. Regulatory Compliance.**

- 6.1 In carrying out their responsibilities under this Agreement and each Work Order, Quintiles and BDSI agree to comply, to the extent applicable, with all laws, rules and regulations, including, but not limited to the Federal Equal Employment Opportunity Act, Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans with Disabilities Act, the Fair Labor Standards Act, the Immigration Reform and Control Act of 1986, the Food, Drug and Cosmetic Act, Section 1128B(b) of the Social Security Act (42 U.S.C. §1320a-7b(b)), and the Prescription Drug Marketing Act. BDSI shall be primarily responsible for compliance, if and to the extent applicable, with the Physician Payment Sunshine Act, Cal. Health & Safety Code s. 119400-119402, and any similar law or regulation of any other governmental unit and shall provide Quintiles with any applicable per physician spending limits arising therefrom. To facilitate the BDSI's compliance with federal and state physician spend reporting requirements, Quintiles will provide its standard monthly excel file that includes data and in a format and format sufficient for BDSI's ready compliance with federal and state reporting requirements.
- 6.2 If Quintiles or its employees become aware of adverse drug experience reports involving the use of any BDSI Product, while performing any Services in connection with the BDSI Product, Quintiles shall notify BDSI \*\*\* and \*\*\*. \*\*\*\*shall deliver to \*\*\* a written copy of such \*\*\*.
- 6.3 Quintiles represents and warrants that neither it nor any of its Affiliates providing Services under this Agreement has been debarred or is subject to debarment pursuant to the the Federal Food, Drug and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder and as may be in effect from time to time (the “Act”) or has been excluded from participating in any federal healthcare program, and Quintiles covenants that it shall not use in any capacity, in connection with the Services to be performed under this Agreement, any person (i) who has been debarred pursuant to Section 306 of the Act, or (ii) is otherwise ineligible to participate in federal healthcare programs. Quintiles further covenants that it will not use in any capacity in connection with the Services to be performed under this Agreement, any person known to Quintiles, after appropriate or reasonable inquiry, who is the subject of a conviction described in such 42 U.S.C. § 1320a-7(a) for which a person can be debarred, suspended or excluded. Quintiles agrees to notify BDSI \*\*\* if it is debarred or it becomes aware of the fact that any Quintiles personnel performing Services under this Agreement is debarred or is the subject of a conviction described in 42 U.S.C. § 1320a-7(a), or if any action, suit, claim, investigation or legal or administrative proceeding is pending or is threatened, relating to the debarment, suspension, exclusion, ineligibility or conviction of Quintiles or any Quintiles personnel providing Services hereunder.
- 6.4 Both parties agree that each party, in fulfilling its obligations under this Agreement, will not violate any applicable law or regulation.



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- 6.5 BDSI shall be solely responsible for responding to any government or regulatory agency concerning use or marketing of BDSI Products, except where (i) such responsibility is expressly transferred to Quintiles in a Work Order; or (ii) to the extent any notice or reporting requirement is by law made directly applicable to Quintiles. Written reports made by Quintiles as a result of any government investigation or audit shall be charged to BDSI \*\*\*; provided such government investigation or audit does not result or arise from Quintiles' negligence, misconduct or breach of this Agreement and/or Work Order. Both Quintiles and BDSI shall provide the other with copies of all written reports, including all applicable documentation, made to any governmental or regulatory agency that implicates the other party in any manner. Both Quintiles and BDSI shall provide the other with a written summary of any oral or telephonic report involving the other party in any respect made to any governmental or regulatory agency. In no event shall Quintiles respond to any agency without the prior consent of BDSI, unless compelled to do so by law, as reasonably determined by competent legal counsel.
- 6.6 \*\*\* shall promptly notify \*\*\* of any information \*\*\* receives regarding any threatened or pending action by a government or regulatory agency that may affect the \*\*\* Products or its ability to fulfill its obligations in this Agreement and/or any Work Order.
- 6.7 \*\*\* shall notify \*\*\* of every instance of actual or suspected fraud or misconduct on the part of a \*\*\* employee promptly after the initial discovery of any suspicious findings or possible evidence of such. \*\*\* shall, at the request of \*\*\*, cooperate with \*\*\* in order to respond, or in formulating a procedure for taking appropriate action.
- 6.8 Subject to the provisions in Article 7, Quintiles shall maintain all sample accountability records (if applicable) for \*\*\* from the date of creation. After \*\*\*, with at least \*\*\* prior notice, Quintiles shall destroy such records unless BDSI has requested their return at BDSI's expense.
- 6.9 Anti-Bribery. Each party agrees that:
- (a) it will not, and will ensure that each of its Representatives will not, (i) offer, promise or give an advantage to another person, or (ii) request, agree to receive or accept a financial or other advantage in violation of any anticorruption laws, rules, regulations and decrees applicable to the respective party (collectively, "Legislation"), including without limitation the United States Foreign Corrupt Practices Act, as amended (the "FCPA. It is each party's responsibility to be familiar with, and comply with, the provisions of the applicable Legislation.
- (b) from time to time, at the reasonable request of the other party, it will confirm in writing that it has complied with its undertakings under subsection (a) above and will provide any information reasonably requested by the other party in support of such compliance.

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**7. Return of BDSI Materials.**

Within \*\*\* after the termination or expiration of the Agreement or any Work Order, all BDSI Confidential Information, BDSI Property and other data owned by BDSI, regardless of the method of storage or retrieval, shall at BDSI's request either be delivered to BDSI in such form as is then currently in the possession of Quintiles, or disposed of, at the direction and written request of BDSI, unless such materials are otherwise required to be stored or maintained by Quintiles as a matter of law or regulation. BDSI shall pay \*\*\* associated with any of the above options that are documented by contemporaneous written records. Quintiles reserves the right to retain, \*\*\* subject to the confidentiality provisions herein, one copy of all materials provided in connection with performance of the Services, to be used to solely to satisfy regulatory requirements or to resolve disputes regarding the Services. For the copy, Quintiles shall store the copy in a secure location, and ensure that only Informed Persons on a need-to-know basis has access to the copy.

**8. Indemnification and Liability Limits.**

- 8.1 Quintiles shall indemnify, defend and hold harmless BDSI, its Affiliates and their Representatives from and against \*\*\* (collectively, “Losses”), joint or several, resulting or arising from \*\*\* to the extent resulting from or arising out of any \*\*\*; all except to the extent such Losses resulted from \*\*\* of BDSI, its Affiliates or their Representatives.
- 8.2 BDSI shall indemnify, defend and hold harmless Quintiles, its Affiliates and their Representatives from and against \*\*\* to the extent resulting from or arising out of \*\*\*; all except to the extent such Losses are determined to have resulted from \*\*\* of Quintiles or its employees.
- 8.3 The party seeking indemnification hereunder (the “Indemnified Party”) shall: (a) give the party obligated to indemnify (the “Indemnifying Party”) \*\*\* notice of any such claim or law suit (including a copy thereof); (b) Indemnified Party and its employees shall fully cooperate with Indemnifying Party and its legal representatives in the investigation and defense of any matter the subject of indemnification; and (c) Indemnified Party shall not unreasonably withhold its approval of the settlement of any such claim, liability, or action by Indemnifying Party covered by this Indemnification provision; provided, however, that Indemnified Party's failure to comply with its obligations pursuant to Section 8.3 shall not constitute a breach of this Agreement nor relieve Indemnifying Party of its indemnification obligations pursuant to Section 9, except to the extent, if any, that Indemnifying Party's defense of the affected claim, action or proceeding actually was materially impaired thereby.
- 8.4 \*\*\* SHALL HAVE \*\*\* FOR ANY \*\*\*. IN ADDITION, IN NO EVENT SHALL THE COLLECTIVE, AGGREGATE LIABILITY \*\*\* OF \*\*\*, OR THEIR RESPECTIVE DIRECTORS, OFFICERS, EMPLOYEES, SUBCONTRACTORS OR AGENTS UNDER THIS AGREEMENT \*\*\*.

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- 8.5 Quintiles shall not be liable to BDSI for claims or losses arising out of the statements or representations of Quintiles employees in furtherance of the Services with respect to BDSI Products to the extent the statements or representations are at the direction of BDSI and conform (in manner, substance and form) to official instructions and written or printed statements or representations made to Quintiles and Quintiles employees by BDSI with respect to the BDSI Products.
- 8.6 In the event that Quintiles, any of its Affiliates or their Representatives is served with or becomes subject to any subpoena, order, judgment, complaint, proceeding, enforcement or other legal process (each, a “Legal Proceeding”) to which BDSI is a party or subject, but Quintiles is not, which Legal Proceeding seeks from Quintiles disclosure of any documents or information related to the Services, then BDSI shall bear and/or reimburse Quintiles for all reasonable third party fees, costs and expenses associated with such Legal Proceeding; provided the Legal Proceeding is not the result of or arises from any negligence or misconduct or breach of this Agreement and/or any Work Order by Quintiles, any of its Affiliates or their Representatives.
- 9 Insurance.**
- \*\*\* shall obtain and maintain in full force and effect, the following insurance during the Term (and any subsequent renewals thereof): \*\*\* shall provide \*\*\* with a certificate of insurance evidencing all coverage herein required, \*\*\* after the effective date of this Agreement and upon each insurance renewal. \*\*\* must provide \*\*\* notice of cancellation or material change in insurance coverage. Insurance obligations set forth herein must be provided by insurance carriers with a rating of not less than A-, VII, as rated by AM Best & Company or equivalent rating agency. Notwithstanding the foregoing, the insurance obligations hereunder may be met by a program of self-insurance supported by actuarial analysis or public financial reports.
- 10. Term and Termination.**
- 10.1 This Agreement shall commence on the date of execution and shall continue until terminated as hereinafter provided (the “Term”). Each Work Order shall include a statement of the Project start date and the Project end date (the “Project Term”).
- 10.2 Except as otherwise set forth in the applicable Work Order, either party may terminate this Agreement or any Work Order without cause at any time by \*\*\* notice to the other party.
- 10.3 Either party may terminate this Agreement by written notice at any time if the other party defaults in the performance of its material obligations under the Agreement or materially breaches the Agreement and does not cure such material default or breach within the Cure Period. Either party may terminate a Work Order by written notice at any time if the other party defaults in the performance of its material obligations under the Work Order Agreement or materially breaches the Work Order. In the event of any such default or

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breach of the Agreement or Work Order, the party declaring the default or breach shall provide the defaulting or breaching party with written notice setting forth the nature of the default or breach, and the defaulting or breaching party shall have \*\*\* to cure the default. If the defaulting party fails to cure the default within the foregoing time period, the other party may terminate the Agreement or Work Order, as the case may be, by written notice to the defaulting or breaching party, which notice shall be effective upon receipt. During the \*\*\* cure period for termination due to default or breach, each party will continue to perform its obligations under the Agreement. If the cure period has expired without a substantial cure of the breach, then the parties shall promptly meet to prepare a close-out schedule, and Quintiles shall cease performing all work not necessary for the orderly close-out of the Services or required by laws or regulations.

- 10.4 Either party may terminate this Agreement by written notice to the other party, effective upon receipt with no right to cure the default, if the other party files a petition for bankruptcy, reorganization or arrangement under any state statute, or makes an assignment for the benefit of creditors or takes advantage of any insolvency statute or similar statute, or if a receiver or trustee is appointed for the property and assets of the party and the receivership proceedings are not dismissed within \*\*\* of such appointment.
- 10.5 In the event this Agreement or a Work Order is terminated for any reason, BDSI shall pay to Quintiles: (a) all Fees for Services rendered which have accrued and are due and owing to Quintiles because of any completed performance of Quintiles’ obligations not under dispute prior to the effective date of termination; and (b) all pass-through expenses actually incurred and documented by contemporaneous, written records by Quintiles prior to the effective date of termination. In the event this Agreement or a Work Order is terminated for any reason *other than* due to a material breach of the Agreement or applicable Work Order by Quintiles, BDSI shall also pay: (c) all actual costs, including time spent by Quintiles personnel (which shall be billed at Quintiles’ standard rates in effect as of the date of the termination notice), incurred to complete activities associated with the termination and close-out of the affected Project(s), provided Quintiles uses commercially reasonable efforts to minimize all actual costs and such actual costs are documented with contemporaneous written records; and (d) any other costs not identified above which have been expressly identified in a Work Order as being due upon termination of such Work Order.

**11. Relationship with Affiliates.**

- 11.1 BDSI agrees that Quintiles may utilize the Services of its corporate Affiliates to fulfill Quintiles’ obligations under this Agreement or any Work Order, and Quintiles shall remain responsible for all such Services performed by its Affiliates. Any Quintiles Affiliate so utilized shall be (i) subject to all of the terms and conditions applicable to Quintiles under this Agreement and the Work Order applicable to such Project(s), including, but not limited to, provisions establishing the standards for performance, (ii) entitled to all rights and protections afforded Quintiles under this Agreement and the Work Order applicable to such Project(s), including, but not limited to, the indemnity and limitation of liability protections

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set forth herein, and (iii) solely responsible for the performance of the Services under such Work Order. Any such Affiliate of Quintiles may execute a Work Order directly and, with respect to the corresponding Project, the rights and obligations of the parties shall be governed by all of the terms and conditions of this Agreement, to the same extent as if such Quintiles Affiliate was a party to this Agreement.

- 11.2 BDSI and Quintiles acknowledge that with prior written approval by BDSI on a case-by-case basis, certain Affiliates of BDSI may utilize the services of Quintiles (and its Affiliates) under this Agreement and under any Work Order. In such event, (i) BDSI shall cause such BDSI Affiliate to acknowledge and be bound by all the terms and conditions of this Agreement and the specific Work Order, and (ii) BDSI shall remain responsible and obligated under this Agreement and the Work Order, as if BDSI was directly receiving the Services provided to such BDSI Affiliate. Any such Affiliate of BDSI may execute a Work Order directly and, with respect to the corresponding Project, the rights and obligations of the parties shall be governed by all of the terms and conditions of this Agreement, to the same extent as if such BDSI Affiliate was a party to this Agreement.
- 11.3 Unless otherwise expressly provided for in this Agreement, Quintiles will not subcontract all or any part of the services provided hereunder without first obtaining BDSI's prior written consent. Quintiles shall require each BDSI-approved subcontractor to execute a written agreement with terms no less restrictive than those set forth in Article 4 of this Agreement. Quintiles further represents and warrants that the services performed by any such subcontractors will be performed in accordance with all the terms and conditions of this Agreement, including the warranties of Section 18.4.

**12. Cooperation.**

All data and information in BDSI's possession or control reasonably necessary for Quintiles to perform the Services under this Agreement or applicable Work Order will be delivered by BDSI to Quintiles. Quintiles shall not be liable to BDSI nor be deemed to have breached this Agreement or any Work Order as a result of errors, delays or other consequences directly and substantially arising from BDSI's failure to timely provide documents, materials or information or to otherwise cooperate with Quintiles in order for Quintiles to timely and properly perform Quintiles' obligations, and any such failure by BDSI shall automatically extend any timelines affected by a time period reasonably commensurate to take into account such failure, unless BDSI agrees in writing to pay any additional, reasonable costs that would be required to meet the original timeline. Nothing set forth in this Article 12 shall remove any liability of Quintiles for its negligence or wilfull misconduct or violation of any municipal, state, and federal laws, rules, and regulations.

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DENOTED WITH “\*\*\*”**

**13. Force Majeure.**

If the performance or observance of this Agreement or any obligation of this Agreement or any Work Order is prevented or delayed by reason outside the control of the affected party, such as an act of God, civil commotion, storm, fire, riots, strikes, legal moratorium (other than FDA action), war or revolution, the party so affected shall, upon prompt notice of such cause being given to the other party, be excused from such performance or observance to the extent of such prevention or during the period of such delay, provided that the party so affected shall use its best efforts to avoid or remove the cause(s) of non-performance and observance with utmost dispatch; and further provided that the prevention or delay is not the result of or arise from the negligence or misconduct of the affected party.

**14. Review of Work; Audit.**

During the term of this Agreement, Quintiles will permit BDSI or a third-party auditor selected by BDSI, who is bound by obligations of confidentiality at least as restrictive as those set forth herein and who is not an entity competitive to Quintiles, at \*\*\* and in a \*\*\* as agreed upon by the parties, but no more frequently than \*\*\*, and at BDSI's expense, to (i) examine the documentation associated with the work performed hereunder to confirm that the Services are being conducted in accordance with the terms herein or in the applicable Work Order, or (ii) audit the financial records related to Quintiles' performance of the Services.

**15. Notices.**

Any notice required or permitted to be given by either party shall be in writing. All notices shall be to the parties and addresses listed below, and shall be deemed given (i) on the date received if delivered personally or sent by facsimile or (ii) one business day after the date sent by a reputable overnight delivery service, or (iii) three (3) days after the date postmarked if sent by regular, registered or certified mail, return receipt requested, postage prepaid.

If to Quintiles:	***
With a copy to:	***
If to BDSI:	***
With a copy to:	***

**16. Assignment.**

\*\*\* shall not have the right or the power to assign any of its rights, or delegate or subcontract the performance of any of its obligations under this Agreement, without the prior written authorization of \*\*\*; provided, however, that the prior written authorization of \*\*\* shall not be required for \*\*\* to assign any of its rights, or delegate or subcontract the performance of any of its obligations hereunder to an Affiliate or as a result of a merger or acquisition; provided the assignee is not a competitor of \*\*\*, in which case, such assignment would

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require \*\*\* prior written consent, which shall not be unreasonably withheld. Notwithstanding anything contained herein to the contrary, \*\*\* shall have the right to assign and transfer this Agreement and any Work Order, if any, in part or in whole, to any other third party that is not a competitor of \*\*\* with \*\*\* prior written consent, which shall not be unreasonably withheld. The Agreement shall inure to the benefit of any permitted assigns, successors in business, or subsidiaries or Affiliates of the parties. Any attempted assignment or transfer in contravention of this Article 16 shall be null and void.

**17. Arbitration.**

Resolution of disputes concerning any aspect of the Services, this Agreement or any Work Order shall be accomplished by good faith negotiations between BDSI and Quintiles, to be commenced within \*\*\* after notice. If necessary, thereafter, resolution of such disputes shall be accomplished, at written request of either party to the other party, by binding arbitration, which shall not interfere with the timely rendering of Services. Arbitration will be pursuant to the Rules of Conciliation and Arbitration of the American Arbitration Association, using a three-person panel of arbitrators, one (1) to be designated by BDSI, one (1) by Quintiles, and a third to be agreed upon by the other two (2) arbitrators. If the two party-appointed arbitrators are unable to agree on a third arbitrator within \*\*\* after the second arbitrator is appointed, the third arbitrator shall be selected by the American Arbitration Association.

**18. Additional Warranties and Representations.**

- 18.1 Quintiles and BDSI warrant and represent to the other that they have the full right and authority to enter into this Agreement and that there is no impediment that would inhibit their ability to perform their respective obligations under this Agreement or any Work Order. Each party further represents that it will not enter into any such agreement during the term of this Agreement.
- 18.2 Quintiles and BDSI agree to perform their obligations hereunder in a timely, professional and competent manner.
- 18.3 BDSI warrants and represents that it possesses good title to, or the right to use, any and all trademarks of the BDSI Products, free and clear of any claims or encumbrances that would impede the performance by either party under the terms of this Agreement or any Work Order. In addition, BDSI owns or controls the patents or appropriate licenses in connection with all BDSI Products to be involved in the Services, and has no knowledge of the existence of any claim or adverse rights which would restrict or prevent BDSI or Quintiles from performing the Services pursuant to this Agreement or a Work Order.

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18.4 Quintiles represents and warrants that:

- i) neither Quintiles nor any of its Representatives who are directly concerned with the performance of the Services has been debarred pursuant to the Federal Food, Drug and Cosmetic Act (“**FDCA**”) or is currently excluded, debarred, suspended, or otherwise ineligible to participate in any federal health care programs or in any federal procurement or non-procurement programs. Moreover, if Quintiles or any of its Representatives who is directly concerned with the performance of the Services subsequently becomes debarred, excluded, suspended or ineligible as set forth in the preceding sentence, or is convicted of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in any federal health care programs but has not yet been excluded, debarred, suspended, or otherwise declared ineligible to participate in those programs, Quintiles agrees immediately to notify BDSI of such event.
- ii) it shall, and shall cause its Representatives to, comply with all municipal, state, and federal laws, rules, and regulations applicable to the performance of the Quintiles’ obligations under this Agreement and any Work Order.

**19. General Provisions**

- 19.1 This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of the State of North Carolina, without giving effect to the principles of conflict of laws. The parties agree that any action or proceeding arising out of or in connection with this Agreement will be venued in a federal or state court of appropriate venue and subject matter jurisdiction located in the State of North Carolina. Each party hereto irrevocably consents to the personal jurisdiction of the courts in the State of North Carolina.
- 19.2 The rights and obligations of BDSI and Quintiles under this Agreement and any Work Order, which by intent or meaning have validity beyond such termination (including, but not limited to, rights with respect to confidentiality, mutual indemnification and liability limitations) shall survive the termination of this Agreement or such Work Order for the terms expressly set forth herein and if no term is provided, indefinitely. Notwithstanding, for the sake of clarity, Articles 1, 2, 3, 4, 6, 7, 8, 9, 15, 16, 17, 18 and 19 and Sections 5.3, 10.3, 10.5, 10.6 and 11.4 shall survive the expiration or termination of this Agreement and any Work Order.
- 19.3 This Agreement contains the entire understandings of the parties with respect to the subject matter herein, and cancels and supersedes all previous agreements (oral and written), negotiations and discussions, dealing with the same subject matter. The parties, from time to time during the term of this Agreement, may modify any of the provisions hereof only by an instrument in writing duly executed by both parties.
- 19.4 References to any Schedule, Appendix, Attachment or Exhibit attached to this Agreement or any Work Order shall be deemed to incorporate the entire contents of the Schedule, Appendix, Attachment or Exhibit by reference, as if it were fully set forth in the Agreement or Work Order to which it is attached.
- 19.5 No failure or delay on the part of a party in either exercising or enforcing any right under this Agreement or any Work Order will operate as a waiver of, or impair, any such right. No single or partial exercise or enforcement of any such right will preclude any other or further



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exercise or enforcement thereof or the exercise or enforcement of any other right. No waiver of any such right will have effect unless given in a signed writing. No waiver of any such right will be deemed a waiver of any other right.

- 19.6 If any part or parts of this Agreement or a Work Order are held to be illegal, void or ineffective, the remaining portions of the Agreement or Work Order shall remain in full force and effect. If any of the terms or provisions are in conflict with any applicable statute or rule of law, then such term(s) or provision(s) shall be deemed inoperative to the extent that they may conflict therewith, and shall be deemed to be modified or conformed with such statute or rule of law. In the event of any ambiguity respecting any term or terms hereof, the parties agree to construe and interpret such ambiguity in good faith in such a way as is appropriate to ensure its enforceability and viability. Neither party shall assert against the other that the compensation arrangement provided in this Agreement or any Work Order is ground for voiding the Agreement or Work Order, or rendering the same unenforceable.
- 19.7 The headings contained in this Agreement and any Work Order are used only as a matter of convenience, and in no way define, limit, construe or describe the scope or intent of any section of this Agreement or such Work Order.
- 19.8 Quintiles agrees promptly to inform BDSI of any event or change in circumstances which may reasonably be expected to negatively affect Quintiles' ability to perform its obligations under this Agreement in the manner contemplated by the parties.

**20. Execution in Counterparts**

- 20.1 This Agreement may be executed in any number of counterparts, each of which when executed and delivered, shall constitute an original, but all of which together shall constitute one agreement binding on all parties, notwithstanding that all parties are not signatories to the same counterpart.
- 20.2 Transmission by fax or by electronic mail in portable document format (pdf) of an executed counterpart of this Agreement shall be deemed to constitute due and sufficient delivery of such counterpart. The parties shall deliver to each other an original counterpart of this Agreement promptly after delivery by fax or electronic mail provided however, that failure by either party to so deliver an original counterpart shall not affect the sufficiency of a fax or electronic mail of such counterpart as provided in the first sentence of this paragraph.

*[Remainder of page left intentionally blank]*

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IN WITNESS WHEREOF, this Agreement has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

**QUINTILES COMMERCIAL US, INC.**

**BDSI**

By: /s/ Kenneth P. Budes  
Name: Kenneth P. Budes  
Title: V.P. Finance  
  
Date: Sept. 29, 2013

By: /s/ Al Medwar  
Name: Al Medwar  
Title: Vice President, Marketing & Corporate Development  
  
Date: 9/27/13